STATEMENT OF
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NATIONAL VETERANS AFFAIRS AND REHABILITATION COMMISSION
THE AMERICAN LEGION
BEFORE THE
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATION
COMMITTEE ON VETERANS' AFFAIRS
UNITED STATES HOUSE OF REPRESENTATIVES
ON
"VENDORS IN THE OR – VA'S FAILED OVERSIGHT OF SURGICAL IMPLANTS"

JANUARY 15, 2014

In January 2011 the Veterans Health Administration (VHA) issued a statement regarding the DePuy Orthopaedics Inc. ASR™ Hip Resurfacing System and the voluntary recall of the product that company initiated in August of 2010[1]. On the surface, the document outlines the process of taking existing stock off the inventory shelves of VHA facilities; however, despite the assurances of the missive, questions remain for veterans who may already have had the surgery. Although VHA claims to be able to prevent future use of the implants, what about veterans who have already received the implants? Is there a tracking system in place to identify veterans who have received faulty surgical implants? How are they contacted? How are the serial numbers of defective products tracked? Is the system in place at VHA robust enough to serve the best interests of the veteran patients?

The indications The American Legion has discovered in answer to these questions, and others, is that flaws still exist with the tracking and implementation of surgical implants in VHA. Through the work of our research through such tools as the System Worth Saving Task Force, which conducts nationwide, on-site investigations of VHA facilities, The American Legion has concerns about three key areas of VHA surgical implant policy, or lack thereof.

1. Lack of a robust system for tracking surgical implants.
2. Questions surrounding patient consent to vendor participation in implant surgery.
3. Possible circumvention of regulations and use of the supply schedule when making decisions about surgical implants.

Tracking Surgical Implants

The Department of Veterans Affairs (VA) Office of the Inspector General (OIG) conducted an audit in 2012 and made recommendations regarding VA's management of their prosthetics supply inventory[2]. In VHA's response, they indicated that they would work to develop a plan to replace the Prosthetic Inventory Package (PIP) and the Generic Inventory Package (GIP) with a more comprehensive system. The target completion date is March 30, 2015. In the interim,

[1] VHA Notice 2011-01 ASR™ HIP SYSTEM RECALL, January 11, 2011
[2] VAOIG Report 11-00312-127 "Audit of Prosthetics Supply Inventory Management

VHA indicated they were working on a VA OI&T patch (VistA Prosthetics patch 101) which was 95% completed.

While reaching this goal by 2015 is indeed laudable, and 2015 is rapidly becoming a critical year for VA to meet strategic goals including the elimination of veteran homelessness and the disability claims backlog, The American Legion would like to see a more detailed timeline implementing these changes and improvements for veterans. Reports through System Worth Saving Task Force visits and contact with VHA employees indicate responsibility for entering serial numbers of implant devices is manual, not automated, and is inconsistently implemented.

Although VHA claims to work to a standard of "removing recalled products from inventory within 24 hours of a recall", there is still no clear policy on how veterans who have already received implants are tracked. It is not enough to cut off the problem at the source, attention must be paid to veterans who are already downstream in the process. Without consistent tracking of implants, including positive identification by serial number and other identifying factors, uncertainty remains as to how veterans are served in the case of recalls. The American Legion would like to see a more comprehensive procedure and policy clearly delineated by Central Office to ensure consistency in all Veterans Integrated Service Networks (VISNs).

Patient Consent to Vendor Presence in the Operating Room

The American Legion recognizes that there may be circumstances when it would be beneficial to have qualified and certified personnel from a vendor present during implant surgeries. Hopefully, in such circumstances the veteran patient would receive a detailed briefing from the medical team serving their needs, and a clear and consistent policy, delineated in regulations, would be followed to ensure this is handled in a proper and ethical manner. Unfortunately, as The American Legion has researched policies regarding this practice, the opposite is true.

Consent to such a procedure, rather than being a separate and important step in the veteran's care plan, is buried in a three page form under the vague heading "**15. Additional Information**[3]" with a paragraph that reads in total:

> *VA hospitals are teaching facilities, and trainees may participate in or observe this treatment/procedure. In certain circumstances, the presence of a vendor representative (company representative) is important to the success of the procedure. Prior to the procedure the representative will sign an agreement to strictly adhere to VA's privacy rules. The representative may provide technical advice but will not physically participate in the procedure. The representative will be closely monitored by the VA treatment team.*

It would be easier to determine if this paragraph is given special attention during pre-surgical briefings; however no clear policy regulations exist, so it is not surprising that informed consent on this aspect is inconsistent. When questioned regarding the policy, VA responded not with their own policy, but referencing the National Center for Ethics in Healthcare. VHA recognized:

1. The presence of vendors in the operating room is a common practice in U.S. health care.

[3] VA Form 10-0431a APR 2008

2. There are broadly accepted professional ethics standards pertaining to the presence of vendors in operating rooms. VA does not have a specific policy pertaining to this practice, but VA providers are expected to follow the professional ethics standards of their profession. When there are broadly accepted professional ethics standards pertaining to a particular practice, VA does not typically reiterate those standards in VA policy.

3. Professional ethics standards explaining the presence of vendors in operating rooms include the following:

    1) http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion8047.page
    2) http://www.ama-assn.org/resources/doc/code-medical-ethics/8047a.pdf
    3) http://www.facs.org/fellows_info/statements/st-33.html

4. Consistent with these standards, the consent form that VA uses for all treatments and procedures (VA Form 10-0431a), and that patients (or their surrogate) must sign prior to undergoing operative procedures, contains the following language:

    VA hospitals are teaching facilities, and trainees may participate in or observe this treatment/procedure. In certain circumstances, the presence of a vendor representative (company representative) is important to the success of the procedure. Prior to the procedure the representative will sign an agreement to strictly adhere to VA's privacy rules. The representative may provide technical advice but will not physically participate in the procedure. The representative will be closely monitored by the VA treatment team.

While adherence to the National Center for Ethics in Healthcare is laudable, the lack of a clearly defined VHA regulation can lead to inconsistent application. Though the above response notes specifically, "The representative may provide technical advice but will not physically participate in the procedure" this is inconsistent with anecdotal accounts specifically noting instances where vendors directly participated in the surgeries. In those cases, even *IF* the veteran was properly briefed pre-surgery about vendor participation, direct participation would be outside the bounds of what the veteran had agreed to. This is disingenuous at best and deceitful at worst.

The American Legion believes VHA must delineate a policy with more clarity and ensure staff in all locations are complying with a clearly directed procedure for informed consent.

Circumventing the Supply Schedule

In 1958, title 38 U.S.C. § 8123 Procurement of Prosthetic Appliances was enacted, which authorized the Secretary to procure prosthetic appliances and necessary services without regard to any other provisions of law. Since then, improvements have been made to the Federal Acquisition Regulations (FAR), and the new FAR is intended to provide an acquisition schedule of prosthetic appliances from approved vendors. Many of those vendors represent Veteran Owned Small Businesses (VOSBs) and Service Disabled Veteran Owned Small Businesses

(SDVOSBs). While the provisions of section 8123 still exist in law and are important in certain circumstances, there is a growing concern that this circumvention is becoming the standard practice, rather than the exception and that raises multiple questions and problems.

The American Legion recognizes there is sometimes a need to go outside the schedule. On a System Worth Saving visit in the past year, American Legion Task Force members spoke to a VA physician who related a story in which he wanted to go outside the schedule to utilize a particular type of stent in a heart surgery. When questioned as to why he did not want to use the stents currently on the supply schedule, the physician cited concerns about the durability of the stents, and stated the choice was made to offer a better long term health prognosis for the veteran.

Obviously, the best health interest of the veterans in the healthcare system is always of paramount importance.

While there may be occasional reasons why a physician would need to operate outside the FAR, The American Legion notes this is increasingly becoming the rule rather than the exception, as noted in the testimony for Federal Supply Schedule (FSS) vendors such as Daniel Shaw, a VOSB participant in a hearing before this subcommittee entitled "Purchasing Perspective: VA's Prosthetics Paradox" in May of 2012.

The American Legion urges VHA to examine further how the interaction with the FSS takes place, and ensure that it is being utilized with the proper balance.

Clearly, this subcommittee has been focused on challenges within the prosthetics arena for some time, and will continue to maintain that focus in the future. On behalf of our National Commander Daniel M. Dellinger, and our 2.4 million members, The American Legion thanks this subcommittee for their diligent attention to the veterans' healthcare system. The American Legion will be watching closely, and hopes to work closely with both VA and Congress to ensure the ultimate outcome is in the veterans' best interest.

For any questions regarding this testimony please contact Ian de Planque, Deputy Legislative Director of The American Legion at (202) 861-2700 or ideplanque@legion.org